UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No.1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

UNITED STATES' RESPONSE TO ADDITIONAL STATEMENT OF FACTS IN SUPPORT OF THE ROXANE DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT

The Roxane Defendants' original Statement of Facts Submitted In Support of Its Motion for Partial Summary Judgment was 297 paragraphs long. In addition to replying to each of the United States' responses to those paragraphs, the Roxane Defendants have also submitted as additional facts paragraphs 298 through 318. The United States responds as follows.

298. Beginning in 1999, the DMERCs' pricing array sheets were divided into two sections: a section that listed the generic products and a section that listed the brand products. (Tab 187, Roxane Ex. 58, Cigna Arrays) The CIGNA DMERC testified that in CIGNA's pricing arrays, the top part of the page is an array of "the generic forms of the drug, the strengths of it. The second section are the brand name products." (Tab 236, 3/13/08 Helton Dep. 85-86, 89,93)

UNITED STATES' RESPONSE: Undisputed that the DMERCs' pricing arrays distinguished between generic and brand products, and undisputed that, in CIGNA's pricing arrays, the generic forms of the drug generally were arranged at the top of the array, with the brand names generally arranged below.

299. Arrays produced by CIGNA show that the CIGNA DMERC often listed Novaplus drugs on the top of the page, along with generic forms of the drug. For example, in its array for the drug Bumetanide for the third quarter of 2001, CIGNA placed "Bumetanide Novaplus" in the top portion *(i.e.,* the generic portion) of its pricing array. (Tab 310, AWQ005-0488)

UNITED STATES' RESPONSE: Disputed. Tab 310 does not refer to an array created by the CIGNA DMERC. Although the array was created by CIGNA, it was created in CIGNA's capacity as a non-DMERC Medicare Part B Carrier. Different employees within CIGNA had responsibility for the Durable Medical Equipment (DME) and non-DME Medicare Part B contracts, respectively. Further responding, the United States does not dispute that the Bumetanide NovaPlus products were classified in the top portion of the pricing array.

300. In its array for the drug Doxorubicin HCl for the third quarter of 2001, CIGNA placed "Doxorubicin Novaplus" in the top portion (*i.e.*, the generic portion) of its pricing array. (Tab 311, AWQ005-0457)

UNITED STATES' RESPONSE: Disputed to the extent that the paragraph refers to the CIGNA DMERC. *See supra* the United States' Response to Paragraph 299. The paragraph is otherwise undisputed.

301. In its array for the drug Doxorubicin HCI for the third quarter of 2002, CIGNA again placed "Doxorubicin Novaplus" in the top portion ((*i.e.*, the generic portion) of its pricing array. (Tab 312, AWP024-557; Tab 313, AWQ005-295; Tab 314, AWQ005-296)

UNITED STATES' RESPONSE: Disputed to the extent that the paragraph refers to the CIGNA DMERC. *See supra* the United States' Response to Paragraph 299. The paragraph is otherwise undisputed.

302. CIGNA listed Doxorubicin Novaplus as a generic product despite the fact that the Redbook for Windows CD update listed Doxurubicin HCI Novaplus in the same format as the listing for Ipratropium Bromide Novaplus. (Tab 315, HHD006-0763-764) That is, the CD contained the generic chemical name, "DOXURUBICIN HCL" in all capital letters, and the word "NOVAPLUS" in all capital letters immediately beneath it. *(Compare id* (Redbook CD print-out for Doxorubicin HCI), *with* (fab 316, AWP038-070S, Redbook CD print-ollt for Ipratopium Bromide))

UNITED STATES' RESPONSE: Disputed to the extent that the paragraph refers to the CIGNA DMERC. The paragraph is otherwise undisputed. *See supra* the United States' Response to Paragraph 299.

303. The Palmetto DMERC listed Diltiazem HCL Novaplus in the generic portion of its December 2002 array for the drug Diltiazem HCL (Tab 317, AWQ028-029979)

UNITED STATES' RESPONSE: Disputed. The Diltiazem HCL Novaplus product was not used to determine reimbursement. The product instead appears in the "package" exclusion section, indicating it was not used by Palmetto to determine the allowed amount. Further answering, the Palmetto DEMRC consistently classified NovaPlus products as brands. *See infra* United States' Response to Paragraph 304.

304. The Palmetto DMERC also listed Cytarabine Novaplus as a generic product in its array for the second quarter of 2003. (Tab 318, AWQ04S-0023) That same array shows that Palmetto also inconsistently listed Blenoxane Novaplus as a brand during that quarter. *(Id.)*

UNITED STATES' RESPONSE: Disputed. Tab 318 does *not* show that Palmetto classified Cytarabine NovaPlus or Blenoxane NovaPlus as generic products. The column entitled "otype" shows either a "B" or a "G," which someone unfamiliar with the originating database might think means brand and generic, respectively. However, that is an incorrect interpretation of the column. (Fauci Exhibit 163 (Stone Decl.), ¶ 12) The "otype" column actually indicates whether the fee for the particular HCPCS code was calculated on the basis of the price of a brand or generic, *not* whether the particular drug product was treated as a brand or a generic. (*Id.*)

Further answering, the Palmetto DMERC consistently classified NovaPlus ipratropium bromide products as brands. (*Id.*, ¶ 6). In accordance with this practice, Palmetto classified Cytarabine NovaPlus and Blenoxane NovaPlus as brands. This can be seen in Fauci Reply

Exhibit 190, which is a reproduction from the pricing database used by Palmetto, and which has been produced to Roxane on production CD AWX0281. That database plainly shows that various NovaPlus products, including Bleomycin Sulfate NovaPlus, Cytarabine NovaPlus, and Floxuridine NovaPlus, were classified as brands. (*Id*., at lines 850, 856, 861 and 868).

305. Other documents confirm that the Palmetto DMERC was uncertain about whether to include Novaplus drugs in their pricing arrays. For example, certain lists produced by Palmetto document potential issues and errors with respect to the prices listed in the arrays. (Tab 319, AWQ028-1S8213) Two of these documents note next to Novaplus drugs, "The NDC pulled on the August Redbook. However, it is a Novaplus source. Novaplus is a buying club. Should we include in the calculation?" (*Id.*; Tab 320, AWQ028-157430)

UNITED STATES' RESPONSE: Undisputed that the documents referenced at Tab 319 and 320 contain the quoted language. The United States does not dispute that personnel within the Palmetto DMERC at times posed questions as to how to classify NovaPlus drugs.

306. Despite the Government's claim that the DMERCs properly disregarded drugs that were "preservative free," documents also show that the DMERCs frequently included preservative free drugs in their pricing arrays. For example, the Cigna DMERC noted for Mutamycinand Mitomycin Novaplus, "AWP is much lower than other companies' products even though listed as Preservative-Free. Should be included for pricing." (Tab 321, AWQ025-1153; Tab 322, AWQ025-1154; Tab 323, AWQ025-1155)

UNITED STATES' RESPONSE: Disputed. The documents referenced at Tabs 321, 322 and 323 do not relate to CIGNA, nor any of the other DMERCs. The documents appear to relate to Empire, which was a non-DMERC Medicare Part B Carrier.

307. The OIG produced documents from its workpapers for the 2001 OIG report on excessive reimbursement for ipratropium bromide. (Tab 324, 2/1/08 Ltr. from Draycott to Counsel) Among that production, the OIG produced a document listing the AWPs for ipratropium bromide products as listed in the April 2001 Redbook for Windows. (Tab 325, HHD157-0226 - 227)

UNITED STATES' RESPONSE: Undisputed.

308. The top portion of that document listed the generic ipratropium bromide products and listed "Generic" in the Column labeled "Trade Name." For example, the Roxane-label

ipratropium bromide NDCs were listed with “Generic” in the “trade name” column. (*Id.*)

UNITED STATES’ RESPONSE: Undisputed.

309. The document listed brand sources with the drug’s proprietary name in the trade name column. For example, Atrovent was listed as “Atrovent” in the “Trade Name” column. (*Id.*)

UNITED STATES’ RESPONSE: Undisputed.

310. The OIG's workpaper listed the three Novaplus-label NDCs at the bottom of the list along with the other generic sources of ipratropium bromide. The OIG workpaper listed the Novaplus NDCs with the word “Generic” in the “Trade Name” column. The word “Novaplus” does not appear anywhere in the OIG workpaper. (*ld.*)

UNITED STATES’ RESPONSE: The United States does not dispute that the OIG’s work paper listed the three NovaPlus-label NDCs at the bottom of the list along with the other generic sources of ipratropium bromide. The United States disputes the materiality of this paragraph, however. The OIG had no role in determining the proper classification of products as brands or generics for purposes of determining Medicare reimbursement.

311. The OIG produced another document from its workpapers listing all pricing for ipratropium bromide. (Tab 326, 11/30/07 Ltr. from Draycott to Counsel) On that document, “Atrovent” is circled and the word "brand" is handwritten in the margin. The Novaplus listings are not circled and do not contain any marginalia. (Tab 327, HHDIOO-0390)

UNITED STATES’ RESPONSE: Undisputed, except the United States disputes the materiality of this paragraph. The OIG had no role in determining the proper classification of products as brands or generics for purposes of determining Medicare reimbursement.

312. The OIG also produced documents from its workpapers regarding the report on “Omission of Drugs From the Federal Upper Limit List in 2001.” (Tab 328, 3/11/08 Draycott Ltr. to Counsel) On those documents is a column labeled “Brand.” In that column, the brand drugs are indicated with the letter “Y.” The generic drugs on this list do not have anything noted in the brand column. (Tab 329, HHD160-0087-122; Tab 330, HHDI 60-001 72-205)

UNITED STATES’ RESPONSE: Undisputed, except the United States disputes the

materiality of this paragraph. The OIG had no role in determining the proper classification of products as brands or generics for purposes of determining Medicare reimbursement.

313. Atrovent, for example, is listed with a "Y" in the "Brand" column on the FUL lists. (Tab 329, HHD160-0107; Tab 330, HHD160-0190)

UNITED STATES' RESPONSE: Undisputed.

314. The Novaplus NDCs, in contrast, are listed on these documents but do not have the letter "Y" in the brand column. These NDCs do not have any notation in the "Brand" column. (Tab 329, HHD160-0108; Tab 330, HHD160-0190)

UNITED STATES' RESPONSE: Undisputed, except the United States disputes the materiality of this paragraph. The OIG had no role in determining the proper classification of products as brands or generics for purposes of determining Medicare reimbursement.

315. The OIG also produced several documents from the files of Deputy Regional Inspector Linda Ragone titled "Data for Quality Check." (Tab 331, 4/13/07 Ltr. from Draycott to Counsel) These documents list drugs by J-Code and NDC, and contain pricing information such as AWP, AMP, and ASP. (Tab 332, HHD047-0010-012; Tab 333, HHD047-0015-027; Tab 334, HHD047-0028-030; Tab 335, HHD047-0031-056) One column on the "Data for Quality Check" documents lists "DRUG:....NAME... This column contains the chemical compound name of the drug, for example "Haloperidol Lactate." (Tab 332, HHD047-0010-012)

UNITED STATES' RESPONSE: Undisputed.

316. Another column of the "Data for Quality Check" documents lists the "LABELER_NAME." For example, "Bedford Laboratories," is listed in this column. (*Id.*)

UNITED STATES' RESPONSE: Undisputed.

317. Several Novaplus drugs are listed in this document with "Novaplus" in the "LABELER_NAME" column and the drugs' chemical compound listed in the "DRUG_NAME" column. (Tab 332, HHD047-0010-012) For example, two drugs under J-Code "J1630" is listed as "NOVAPLUS" under "LABELER_NAME" and "Haloperidol Lactate" under "DRUG_NAME." (*Id.*)

UNITED STATES' RESPONSE: Undisputed, except the United States disputes the materiality of this paragraph. The OIG had no role in determining the proper classification of

products as brands or generics for purposes of determining Medicare reimbursement.

318. In fact, all Novaplus drugs are listed on these documents with "NOVAPLUS" under the "LABELER-NAME" column and the chemical compound name of the drug listed in the "DRUG_NAME" column. (Tab 333, HHD047-0015-027; Tab 334, HHD047-0028-030; Tab 335, HHD047-0031-056)

UNITED STATES' RESPONSE: Undisputed, except the United States disputes the materiality of this paragraph. The OIG had no role in determining the proper classification of products as brands or generics for purposes of determining Medicare reimbursement.

Respectfully submitted,

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DATED: September 22, 2009

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ James J. Fauci
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Dated: September 22, 2009 Assistant U.S. Attorney